KANSAS DEPARTMENT OF HEALTH & ENVIRONMENT

Division of Health & Environmental Laboratories

ENVIRONMENTAL LABORATORY ACCREDITATION GLOSSARY

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Note: These definitions maybe subject to change as the National Environmental Laboratory Accreditation Conference (NELAC) glossary is modified.

(1) “Acceptance criteria” means specified limits placed on characteristics of an item, process, or service defined in requirement documents.

(2) “Accuracy” means the degree of agreement between an observed value and an accepted reference value. Accuracy includes a combination of random error (precision) and systematic error (bias) components which are due to sampling and analytical operations; a data quality indicator.

(3) “Batch” means environmental samples that are prepared or analyzed together, or both, with the same process and personnel, using the same lot(s) of reagents. A preparation batch is composed of one to 20 environmental samples of the same NELAC-defined matrix, meeting the above mentioned criteria and with a maximum time between the start of processing of the first and last sample in the batch to be 24 hours. An analytical batch is composed of prepared environmental samples (extracts, digestates or concentrates) which are analyzed together as a group. An analytical batch can include prepared samples originating from various environmental matrices and can exceed 20 samples.

(4) “Blank” means a sample that has not been exposed to the analyzed sample stream in order to monitor contamination during sampling, transport, storage or analysis. The blank is subjected to the usual analytical and measurement process to establish a zero baseline or background value and is sometimes used to adjust or correct routine analytical results. Blanks include:

(A) “Equipment blank” means a sample of analyte-free media which has been used to rinse common sampling equipment to check effectiveness of decontamination procedures.

(B) “Field blank” means a blank prepared in the field by filling a clean container with pure water and appropriate preservative, if any, for the specific sampling activity being undertaken.

(C) “Instrument blank” means a clean sample processed through the instrumental steps of the measurement process; used to determine instrument contamination.

(D) “Method blank” means a sample of a matrix similar to the batch of associated samples (when available) that is free from the analytes of interest and is processed simultaneously with and under the same conditions as samples through all steps of the analytical procedures, and in which no target analytes or interferences are present at concentrations that impact the analytical results for sample analyses.

(E) “Reagent blank” and “method reagent blank” mean a sample consisting of reagent(s), without the target analyte or sample matrix, introduced into the analytical procedure

at the appropriate point and carried through all subsequent steps to determine the contribution of the reagents and of the involved analytical steps.

(5) “Blind sample” means a sub-sample for analysis with a composition known to the submitter. The analyst/laboratory may know the identity of the sample but not its composition. It is used to test the analyst's or laboratory's proficiency in the execution of the measurement process.

(6) “Calibration” means a set of operations that establish, under specified conditions, the relationship between values of quantities indicated by a measuring instrument or measuring system, or values represented by a material measure or a reference material, and the corresponding values realized by standards.

(A) In calibration of support equipment the values realized by standards are established through the use of Reference Standards that are traceable to the International System of Units (SI).

(B) In calibration according to test methods, the values realized by standards are typically established through the use of reference materials that are either purchased by the laboratory with a certificate of analysis or purity, or prepared by the laboratory using support equipment that has been calibrated or verified to meet specifications.

(7) “Calibration curve” means the graphical relationship between the known values, such as concentrations, of a series of calibration standards and their instrument response.

(8) “Calibration method” means a defined technical procedure for performing a calibration.

(9) “Calibration standard” means a substance or reference material used to calibrate an instrument.

(10) “Certified reference material” and “CRM” mean a reference material one or more of whose property values are certified by a technically valid procedure, accompanied by or traceable to a certificate or other documentation which is issued by a certifying body.

(11) “Chain of custody form” means a record that documents the possession of the samples from the time of collection to receipt in the laboratory. This record generally includes: the number and types of containers; the mode of collection; collector; time of collection; preservation; and requested analyses.

(12) “Confirmation” means verification of the identity of a component through the use of an approach with a different scientific principle from the original method. These may include, but are not limited to second column confirmation, alternate wavelength, derivatization, mass

spectral interpretation, alternative detectors or additional cleanup procedures.

(13) “Conformance” means an affirmative indication or judgement that a product or service has met the requirements of the relevant specifications, contract, or regulation; also the state of meeting the requirements.

(14) “Corrective action” means the action taken to eliminate the causes of an existing nonconformity, defect or other undesirable situation in order to prevent recurrence.

(15) “Data audit” means a qualitative and quantitative evaluation of the documentation and procedures associated with environmental measurements to verify that the resulting data are of acceptable quality.

(16) “Data reduction” means the process of transforming raw data by arithmetic or statistical calculations, standard curves, concentration factors, and collation into a more useable form.

(17) “Demonstration of capability” means a procedure to establish the ability of the analyst to generate acceptable accuracy.

(18) “Detection limit” means the lowest concentration or amount of the target analyte that can be identified, measured, and reported with confidence that the analyte concentration is not a false positive value. See method detection limit.

(19) “Document control” means the act of ensuring that documents (and revisions thereto) are proposed, reviewed for accuracy, approved for release by authorized personnel, distributed properly and controlled to ensure use of the correct version at the location where the prescribed activity is performed.

(20) “Holding times” and “maximum allowable holding times” mean the maximum times that samples may be held prior to analysis and still be considered valid or not compromised.

(21) “Internal standard” means a known amount of standard added to a test portion of a sample as a reference for evaluating and controlling the precision and bias of the applied analytical method.

(22) “International system of units” and “SI” mean the coherent system of units adopted and recommended by the general conference on weights and measures.

(23) “Laboratory control sample” means a sample matrix, free from the analytes of interest, spiked with verified known amounts of analytes or a material containing known and

verified amounts of analytes. It is generally used to establish intra-laboratory or analyst specific precision and bias or to assess the performance of all or a portion of the measurement system.

(24) "Laboratory duplicate" means aliquots of a sample taken from the same container under laboratory conditions and processed and analyzed independently.

(25) "Legal chain of custody protocols" means procedures employed to record the possession of samples from the time of sampling until analysis and are performed at the special request of the client. These protocols include the use of a chain of custody form that documents the collection, transport, and receipt of compliance samples by the laboratory. In addition, these protocols document all handling of the samples within the laboratory.

(26) "Limit of detection" and "LOD" mean an estimate of the minimum amount of a substance that an analytical process can reliably detect. An LOD is analyte-and matrix-specific and may be laboratory-dependent.

(27) "Limits of quantitation" and "LOQ" mean the minimum levels, concentrations, or quantities of a target analyte that can be reported with a specified degree of confidence.

(28) "Manager" means the individual designated as being responsible for the overall operation, all personnel, and the physical plant of the environmental laboratory. A supervisor may report to the manager. In some cases, the supervisor and the manager may be the same individual.

(29) "Matrix" means the substrate of a test sample. These matrix distinctions shall be used for purposes of batch and quality control requirements.

(A) "Aqueous" means any aqueous sample excluded from the definition of Drinking Water matrix or Saline/Estuarine source. Includes surface water, groundwater, effluents, and TCLP or other extracts.

(B) "Drinking water" means any aqueous sample that has been designated a potable or potential potable water source.

(C) "Saline/Estuarine" mean any aqueous sample from an ocean or estuary, or other salt water source such as the Great Salt Lake.

(D) "Non-aqueous liquid" means any organic liquid with <15% settleable solids.

(E) "Biological tissue" means any sample of a biological origin such as fish tissue, shellfish, or plant material. Such samples shall be grouped according to origin.

(F) "Solids" means soils, sediments, sludges and other matrices with >15% settleable solids.

(G) "Chemical waste" means a product or by-product of an industrial process that results in a matrix not previously defined.

(H) "Air and emissions" means whole gas or vapor samples including those

contained in flexible or rigid wall containers and the extracted concentrated analytes of interest from a gas or vapor that are collected with a sorbent tube, impinger solution, filter, or other device.

(30) “Matrix spike” means a sample prepared by adding a known mass of target analyte to a specified amount of matrix sample for which an independent estimate of target analyte concentration is available. Matrix spikes are used, for example, to determine the effect of the matrix on a method's recovery efficiency.

(31) “Matrix spike duplicate” means a second replicate matrix spike prepared in the laboratory and analyzed to obtain a measure of the precision of the recovery for each analyte.

(32) “Measurement quality objectives” and “MQOs” mean the desired sensitivity, range, precision, and bias of a measurement.

(33) “Measurement system” means a test method, as implemented at a particular laboratory, and which includes the equipment used to perform the test and the operator(s).

(34) “Method” means a logical sequence of operations, described generically, used in the performance of measurements.

(35) “Method detection limit” means a way to establish a Limit of Detection, defined as the minimum concentration of a substance (an analyte) that can be measured and reported with 99% confidence that the analyte concentration is greater than zero and is determined from analysis of a sample in a given matrix containing the analyte.

(36) “National institute of standards and technology” and “NIST” mean an agency of the US department of commerce's technology administration that is working with EPA, states, NELAC, and other public and commercial entities to establish a system under which private sector companies and interested states can be accredited by NIST to provide NIST-traceable proficiency testing (PT) to those laboratories testing drinking water and wastewater.

(37) “National environmental laboratory accreditation conference” and “NELAC” mean a voluntary organization of state and federal environmental officials and interest groups purposed primarily to establish mutually acceptable standards for accrediting environmental laboratories. A subset of NELAP.

(38) “National environmental laboratory accreditation program” and “NELAP” mean the overall National Environmental Laboratory Accreditation Program of which NELAC is a part.

(39) “Negative control” means measures taken to ensure that a test, its components, or the

environment do not cause undesired effects, or produce incorrect test results.

(40) “NELAC standards” means the plan of procedures for consistently evaluating and documenting the ability of laboratories performing environmental measurements to meet nationally defined standards established by the national environmental laboratory accreditation conference.

(41) “Performance audit” means the routine comparison of independently obtained qualitative and quantitative measurement system data with routinely obtained data in order to evaluate the proficiency of an analyst or laboratory.

(42) “Positive control” means measures taken to ensure that a test or its components, or both, are working properly and producing correct or expected results from positive test subjects.

(43) “Precision” means the degree to which a set of observations or measurements of the same property, obtained under similar conditions, conform to themselves; a data quality indicator. Precision is usually expressed as standard deviation, variance or range, in either absolute or relative terms.

(44) “Preservation” means refrigeration or reagents, or both, added at the time of sample collection or later, to maintain the chemical or biological integrity of the sample or both.

(45) “Procedure” means a specified way to carry out an activity or a process. Procedures can be documented or not.

(46) “Protocol” means a detailed written procedure for field or laboratory operation, or both, which must be strictly followed.

(47) “Quality assurance” and “QA” mean an integrated system of activities involving planning, quality control, quality assessment, reporting and quality improvement to ensure that a product or service meets defined standards of quality with a stated level of confidence.

(48) “Quality assurance project plan” and “QAPP” mean a formal document describing the detailed quality control procedures by which the quality requirements defined for the data and decisions pertaining to a specific project are to be achieved.

(49) “Quality control” and “QC” mean the overall system of technical activities whose purpose is to measure and control the quality of a product or service so that it meets the needs of users.

(50) “Quality control sample” and “QC sample” mean a sample used to assess the performance of all or a portion of the measurement system. QC samples may be Certified

Reference Materials, a quality system matrix fortified by spiking, or actual samples fortified by spiking.

(51) “Quality manual” means a document stating the management policies, objectives, principles, organizational structure and authority, responsibilities, accountability, and implementation of an agency, organization, or laboratory, to ensure the quality of its product and the utility of its product to its users.

(52) “Quality system” means a structured and documented management system describing the policies, objectives, principles, organizational authority, responsibilities, accountability, and implementation plan of an organization for ensuring quality in its work processes, products and services. The quality system provides the framework for planning, implementing, and assessing work performed by the organization and for carrying out required QA and QC.

(53) “Raw data” means any original factual information from a measurement activity or study recorded in a laboratory notebook, worksheets, records, memoranda, notes, or exact copies thereof that are necessary for the reconstruction and evaluation of the report of the activity or study. Raw data may include photography, microfilm or microfiche copies, computer printouts, magnetic media, including dictated observations, and recorded data from automated instruments. If exact copies of raw data have been prepared, the exact copy or exact transcript may be submitted.

(54) “Reference material” means a material or substance one or more properties of which are sufficiently well established to be used for the calibration of an apparatus, the assessment of a measurement method, or for assigning values to materials.

(55) “Reference standard” means a standard, generally of the highest metrological quality available at a given location, from which measurements made at that location are derived.

(56) “Reference toxicant” means the toxicant used in performing toxicity tests to indicate the sensitivity of a test organism and to demonstrate the laboratory's ability to perform the test correctly and obtain consistent results.

(57) “Replicate analyses” means the measurements of the variable of interest performed identically on two or more sub-samples of the same sample within a short time interval.

(58) “Sample tracking” means procedures employed to record the possession of the samples from the time of sampling until analysis, reporting, and archiving. These procedures include the use of a chain of custody form that documents the collection, transport, and receipt of compliance samples to the laboratory. In addition, access to the laboratory is limited and controlled to protect the integrity of the samples.

(59) “Selectivity” means the capability of a test method or instrument to respond to a target substance or constituent in the presence of non-target substances.

(60) “Sensitivity” means the capability of a method or instrument to discriminate between measurement responses representing different levels of a variable of interest.

(61) “Spike” means a known mass of target analyte added to a blank sample or sub-sample; used to determine recovery efficiency or for other quality control purposes.

(62) “Standard” means the document describing the elements of laboratory accreditation that has been developed and established within the consensus principles of NELAC and meets the approval requirements of NELAC procedures and policies.

(63) “Standard operating procedures” and “SOPs” mean a written document which details the method of an operation, analysis or action whose techniques and procedures are thoroughly prescribed and which is accepted as the method for performing certain routine or repetitive tasks.

(64) “Standard method” means a test method issued by an organization generally recognized as competent to do so.

(65) “Standardized reference material” and “SRM” mean a certified reference material produced by the U.S. National Institute of Standards and Technology or other equivalent organization and characterized for absolute content, independent of analytical method.

(66) “Statistical minimum significant difference” and “SMSD” mean the minimum difference between the control and a test concentration that is statistically significant; a measure of test sensitivity or power. The power of a test depends in part on the number of replicates per concentration, the significance level selected, and the type of statistical analysis. If the variability remains constant, the sensitivity of the test increases as the number of replicates is increased.

(67) “Supervisor” means the individual(s) designated as being responsible for a particular area or category of scientific analysis. This responsibility includes direct day-to-day supervision of technical employees, supply and instrument adequacy and upkeep, quality assurance/quality control duties and ascertaining that technical employees have the required balance of education, training and experience to perform the required analyses.

(68) “Surrogate” means a substance with properties that mimic the analyte of interest. It is unlikely to be found in environment samples and is added to them for quality control purposes.

(69) “Technical Director” means the individual(s) who has overall responsibility for the technical operation of the environmental testing laboratory.

(70) “Test” means a technical operation that consists of the determination of one or more characteristics or performance of a given product, material, equipment, organism, physical phenomenon, process or service according to a specified procedure. The result of a test is normally recorded in a document sometimes called a test report or a test certificate.

(71) “Test method” means an adoption of a scientific technique for performing a specific measurement, as documented in a laboratory SOP or as published by a recognized authority.

(72) “Test sensitivity/Power” means the minimum significant difference (MSD) between the control and test concentration that is statistically significant. It is dependent on the number of replicates per concentration, the selected significance level, and the type of statistical analysis.

(73) “Tolerance chart” means a chart in which the plotted quality control data is assessed via a tolerance level based on the precision level judged acceptable to meet overall quality/data use requirements instead of a statistical acceptance criteria.

(74) “Traceability” means the property of a result of a measurement whereby it can be related to appropriate standards, generally international or national standards, through an unbroken chain of comparisons.

(75) “Validation” means the confirmation by examination and provision of objective evidence that the particular requirements for a specific intended use are fulfilled.

(76) “Verification” means confirmation by examination and provision of evidence that specified requirements have been met.

(77) “Work cell” means a well-defined group of analysts that together perform the method analysis. The members of the group and their specific functions within the work cell must be fully documented.

(78) “Working range” means the difference between the Limit of Quantitation and the upper limit of measurement system calibration.